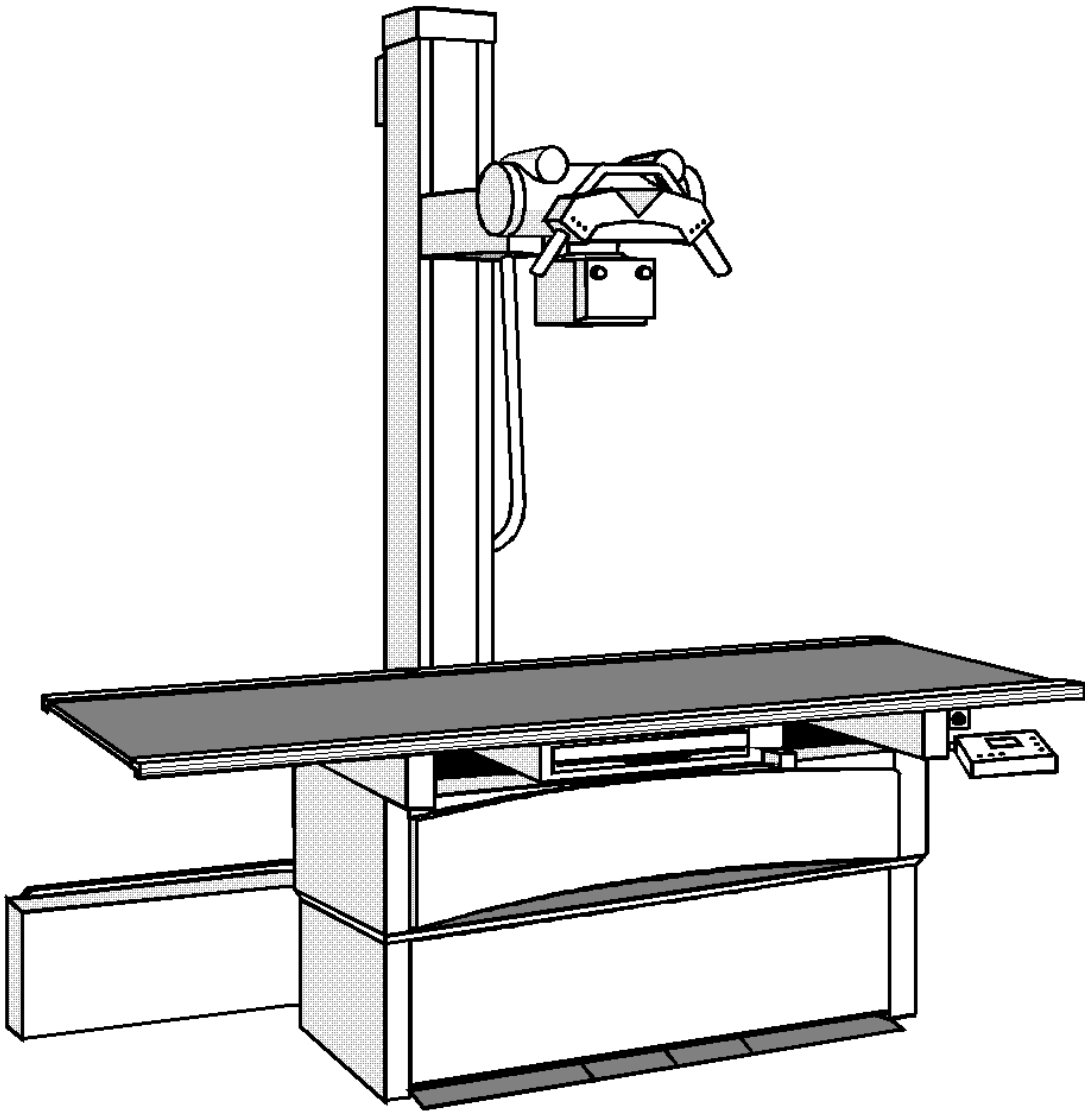
OPERATING INSTRUCTIONS

Combi Elevator Tomo-2



CE 0125

English Edition

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CONTENTS Page

Technical Safety Procedures

- Regulations 3

Product Safety

- Electrical safety 4
- Mechanical safety 4
- Danger of Injury 4
- X-Ray Protection. 5
- Explosion protection 6
- Interference suppression 6
- Classification of product 6
- EC Conformity 6
- Environment condition 6
- Disposal of equipment 6

Design Features

- Conception 7

General

- Brief Description 8
- Range of Application 9

Installation

- Floor Space Required 10
- Room Height 10
- Power 10
- Mains 10
- AL- weakening equivalent 10

Operating Elements

- Arrangement 11
- Meaning of Symbols/Function 12
- Adjustment of the exposure position/exposure 17
- Tomo exposure 19
- Optional accessories 20

Maintenance

- Important note 22
- Operator`s service and maintenance 22
- Periodic maintenance 22
- Cleaning 22
- Disinfection 23
- The Council Directive 93/42EEC on Medical Devices 23

Location of Name Plate

- Labeling 24

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Important Note:

To ensure proper operation of this product it is essential that the service personnel is familiar with the **"Operating Instructions"** which should be studied carefully before use.

Special attention is to be given to the chapter "Safety Notes".

The equipment must be used in accordance with the safety procedures described below, and must not be used for purposes other than those for which it was designed. The equipment may only be used by persons having recognized qualification, including adequate training in radiation protection, authorizing them to perform the examination or treatment carried out.

It is the responsibility of the user to ensure that the government regulations are observed in the installation and operation of the equipment.

Technical safety note:

Regulations

If legal regulations govern the operation of the above equipment, it is the responsibility of the operator to observe them.

For the safety of patients, operators and others, as well the efficient functioning of the equipment it is necessary to have periodic service inspections at 12-month intervals according to the maintenance schedule. Please apply to your service organisation for inspection and maintenance.

Inspections intervals must by all means meet the requirements of the respective legislation or government regulations.

Changes and additions to the product must comply with the relevant legislation as well as with the accepted standards of good manufacturing practice.

As manufacturer of electromedical systems, we assume responsibility for the safety of the equipment only if maintenance, repairs and changes are carried out exclusively by us or third parties expressly authorised by us to do so, and if defective parts relating to the safety of the equipment are replaced by genuine spare parts.

We recommend that the service personnel is being asked to issue a certificate specifying the kind and extend of things or work ranges. The certificate should also show the date of repair, the name of the service company and the signature of the technician.

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Before operating the equipment, the operator must check all devices concerning the safe and efficient functioning.
Please see daily check in chapter Maintenance.
If the user of this equipment likes to combine the unit with other units, components or assemblies and this can not be made clear from the technical data, he must question us as manufacturer or another expert to make sure that the safety of the patients and operator is given by the planned combination.

Product Safety

Electrical safety

Only trained service personnel are permitted to remove covers and panels from the x-ray equipment .

In the Federal Republic of Germany, the electrical installation of rooms used for medical purposes must conform to the provisions of the VDE Standard 0107. In all other countries, the provisions of the applicable local laws and regulations have priority.
The unit is only prepared for solid installation with an all poled separation from the power (IEC 601, Kap. 57.1).

Mechanical safety

It is the responsibility of the operator to ensure safety of patient while the unit is in operation by visual check, proper patient positioning, and use of devices that are provided.

Rest risk:

During proper operation and in case that a first mistake may accur there will be no damage to patient and/or environment.

Danger of injury

The arrows in the illustration show areas which present potential Danger of Injury to operating personnal and patient from the equipment motion.

See next page.

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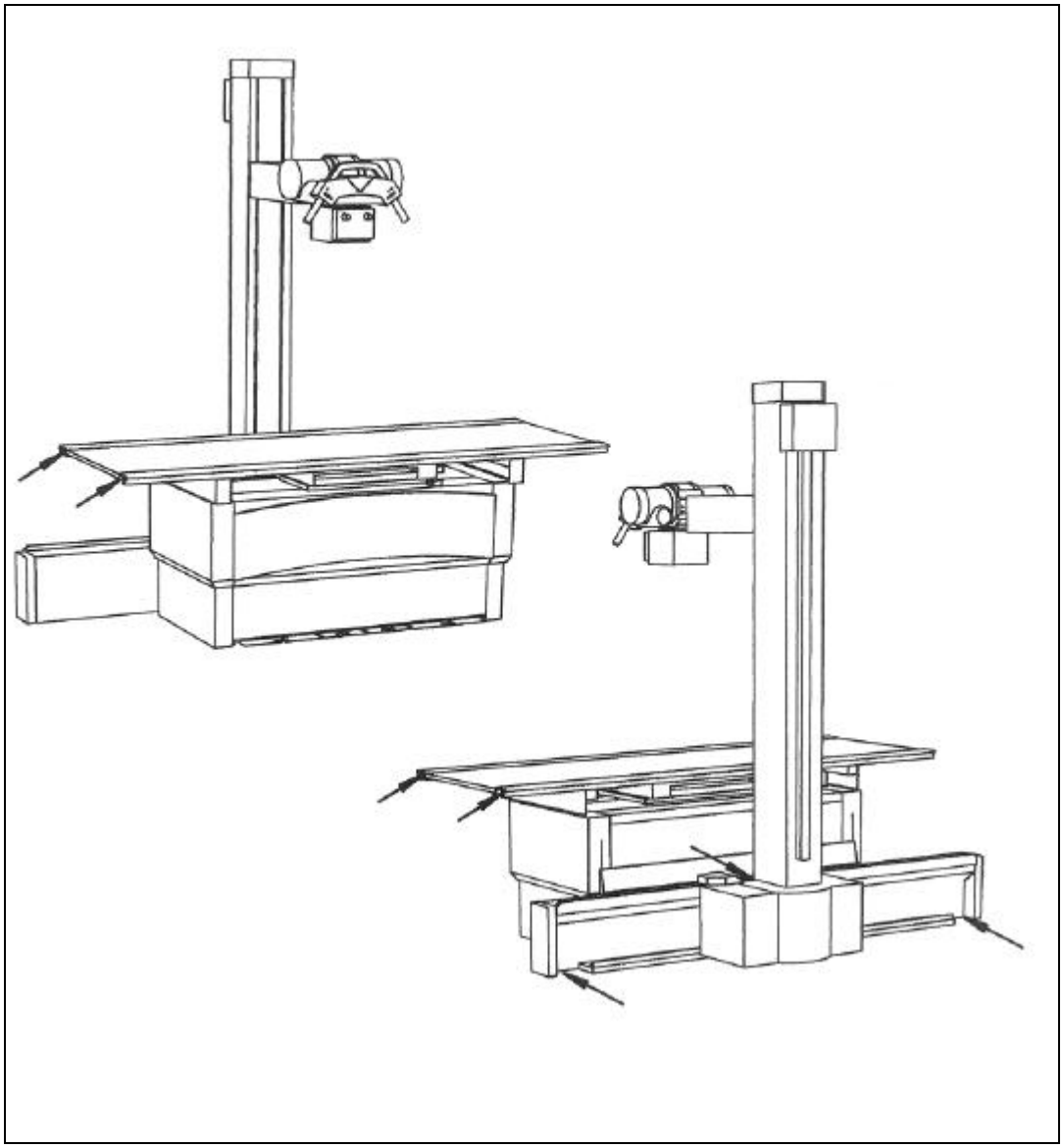

X-Ray Protection.

The unit has no controls with which radiation could be triggerd.
Exposure is triggerd only from the radiation-protected location of the generator.
The general radiation-protection measures must be observed.

In addition, we recommend the following:

1 Set the tube current as low as possible .
2 Limit the radiation field to the maximum possible extent.
3 Keep as far away as possible.
4 Provide radiation protection for the patient.

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Explosion Protection

This equipment is not designed for use in areas where explosion hazard can take place.
Only skin cleaning agents may be used which form non-explosive mixtures with air.

Interference Suppression

The equipment complies with the EMC-requirements of the guideline 89/336 EWG.

Special board International Electronic Commission (IEC). This unit complies to EN 55011 and the reference value is according EN 55011 Group 1 Class B the international electrotechnical committee (IEC).

Classification of product

The equipment complies to the protection degree of Class 1 and for protection against electric shock Type B.

EC Conformity

The Combi Elevator Tomo-2 to which this declaration relates fulfills the essential requirements for safety of medical electrical equipment and follows the provisions of Medical Device Directive 93/42 EEC part 11 para. 3 according the procedure in annex II.
The CE-Mark is only applicable for the product without X-ray components and Bucky.

The declaration of EC-conformity can be sent to you by request:
Write to:
Hans Pausch
Röntgengerätebau
c/o Quality Assurance Sys. Mgr.
Postfach 28 60
D-91016 Erlangen
Fax #: ..49 9131 99 24 22

Enviroment Condition

Surrounding temperatur range	10° C to 40° C
Humidity	20% to 80%
Atmospheric pressure	700 hPa to 1100 hPa

Disposal of equipment

Legal waste disposal regulations may apply to the disposal of this product. To avoid causing damage to the environment and personal injury, we recommend that you contact your Customer Services representative before permanently removing this product from service.

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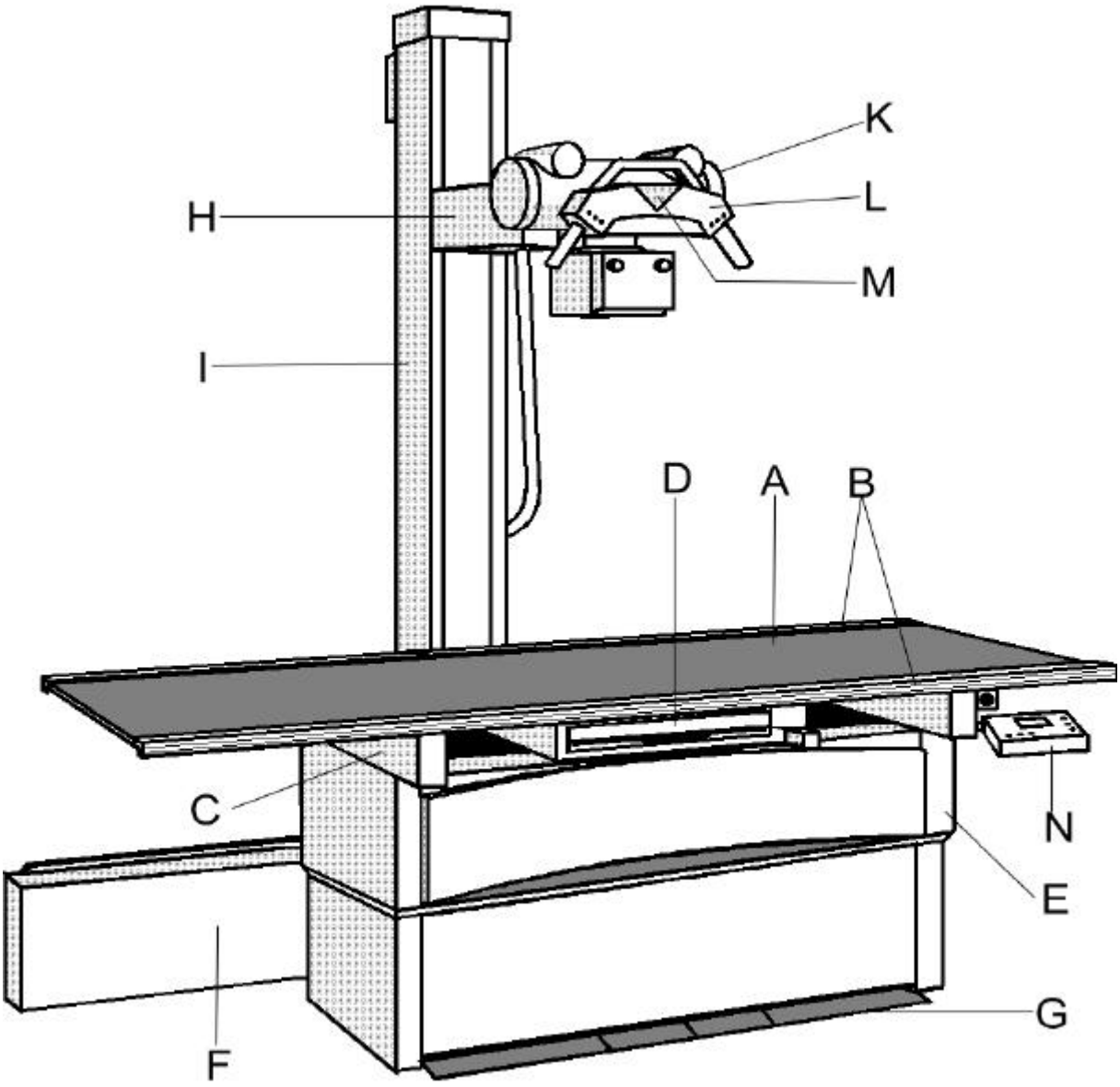
Design Features

Constructional Conception



A Table top, floating, manually movable, scratch-proof
B Profile rail with trim cover, smooth, accepts accessories
C Upper table frame
D Bucky unit, movable
E Table base, solid, vibration-free
F Guide rails for tube stand
G Foot treadle
H Vertical carriage with X-ray tube support arm
I Column, rotatable
K X-ray tube
L Control handle
M Protractor
N Control-panel for Tomo

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General

Short description

The equipment consists of a motor-driven elevating Bucky table with coordinatus table top and Bucky carriage as well as a floor mounted column stand for X-ray tube unit, collimator and control arm including a totally integrated tomography device for linear blurring movement without mechanical coupling.

The solid, vibration-free table base and the rail stand with column form one unit.

The large and 2.20 m long, floating table top is manually movable and locks electromagnetically. The table top is provided for a maximum patient weight of 136 kg. For fast and easy positioning of the patient, it allows spacious lateral travel: 60 cm to the left, 50 cm to the right and ± 12 cm transversely.

Especially for patient comfort and easy cleaning, the table top offers a scratch-proof surface (Resopal) and trim-covered, smooth profile rails on both sides, which can accept accessories.

The Bucky carriage takes up cassette trays as supplied by any reknowned manufacturer. In longitudinal direction, it is manually moved and electromagnetically locked. The shortest possible OFD of 70 mm guarantees images of superior geometrical proportion. Low radiation absorption by the table top reduces the X-ray amount. The brake of the Bucky is released by a push-button on the operating handle.

The foot treadle along the table base allows the release of the elctromagnetic table top brakes.

The tube stand for the X-ray tube support arm and tube is moved on the rail stand parallel to the longitudinal table axis.

The X-ray tube with collimator and control handle for the tube stand is supported by a lateral arm fixed to the vertical carriage. Vertical movement and rotation of the tube around the longitudinal axis of the lateral arm permit vertical, horizontal or oblique beam projections. Each position is electromagnetically locked.

The X-ray tube with column stand rotates around the vertical column axis and catches mechanically at angles of 0° (basic position), ± 90° (for lateral exposures).

The standard tube support is intended for DIN 6836 flanged plate C.
The max. weight of the X-ray tube and collimator must not exceed 40 kg.

For operating there are 3 operating methods from the control panel while pushing the key available:

Table mode - the automatic tube stand - Bucky linkage will adjust automatically the Bucky in their travel range to the middle of the column. Exact positioning of the tube at 0° and ± 90°.

Wall mode - while pushing the key two (adjustable while mounting) SIDs will be motorized positioned while the tube rotates in direction of wall stand. By manual movement of the column is an automaticly stop at the SID`s.

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Tomo mode - while pushing the Prep-key the column and the Bucky drive into central position. After adjusting the tomography a test run or a linear blurring movement is possible. Tomography starts from direction of wall stand.

The totally integrated, microprocessor controlled tomography allows linear blurring movement in Tomo mode.
The tomography exposure can be made with 8°, 20°, 30° and 40° tomo angles from 0-24 cm tomography layer height. There are 2 exposure times for each tomo angle available. These tomo times can be programmed in correspondance with the Generator while installing.

The operator will be guided through the programme from the display of the control panel.

Range of use

The equipment is an universal X-ray examination system for doctors´ practices as well as for hospitals. It provides high-quality gridded exposures and linear blurring movement on lying patients. Large travel of the table top and uncomplicated functioning facilitate operation and increase patient comfort. A special cassette holder is available for lateral exposures. With a Bucky wall stand or a cassette stand, exposures can also be made with patients standing or sitting. Without requiring wall and ceiling fixtures, the equipment easily adjust to change in location.

Prerequisition

For safe and efficient operation of this product the personnel must be familiar with the operating instructions. The chapter on „Safety procedures“ deserves special attention.

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Installation Requirements

Floor space

The system is designed for stationary operation. The approximate floor space required measures 330 cm x 152 cm. An additional 20 cm minimum distance must be kept between tube stand and wall.

Height of room

The tube stand height is 234 cm. Installation requires a minimum room height of 245 cm.
The table top of the equipment has a working height of 75 cm above floor.

Power

The system is equipped for single-phase alternating current with fixed installation. Two versions are available, depending on order. The unit is only prepared for solid installation with an all poled separation from the power (IEC 601, Kap. 57.1).
Without transformer, the system corresponds to nominal ratings as follows:

Nominal voltage:	230 V AC	115 V AC
Nominal current:	6 A	12 A
Rated frequency:	50/60 Hz	50/60 Hz
Nominal capacity:	1380 VA	1380 VA

Mains

The mains connection requires a 30 mA circuit breaker to be installed by the customer. The electrical installation must meet the relevant legislation, e.g. VDE 0107, IEC/SC 62A.

AL-equivalent

The weakening equivalent of the table top (patient pos. table top) is 0,7 mm.

According to:

DIN EN 60601-1-3 mit 100 kV und HWS 3,7 mm AL
and FDA 21 CFR § 1020.30 (n) mit 100 kV und HWS 2,7 mm AL.

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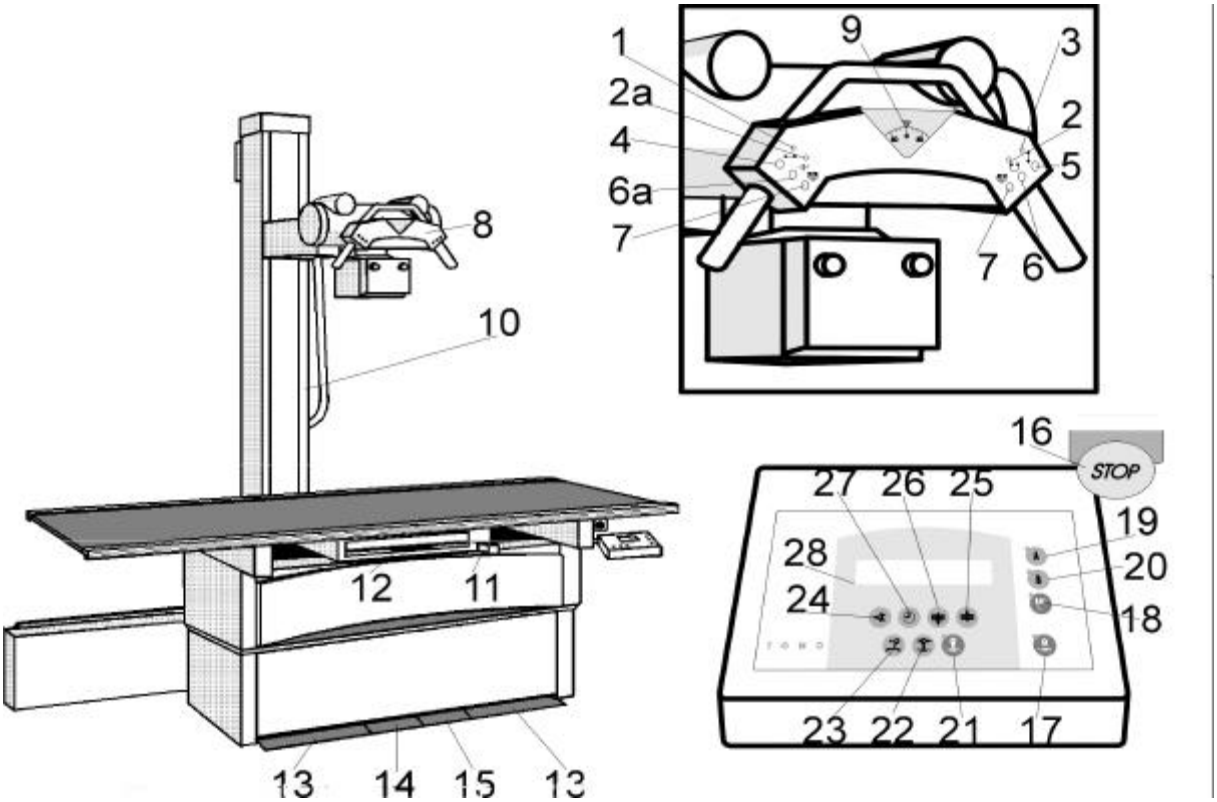
Arrangement



1 Green LED lights when the Bucky is centered to the column
2 Green LED lights when the x-ray tube assembly rotation is catched
2a Green LED lights when the table exposure height
3 Green LED lights when the preferred SID is reached.
4 Switch for horizontal movement of the column
5 Switch for vertical movement of the x-ray tube ass.
6 Switch for tube rotation
6a Safety switch
7 Switch for release of all column brakes
8 Control handle with handgrips
9 Protractor
10 Rotation of tube stand by abrupt movement in appropriate direction on control handle
11 Push button for Bucky
12 Hand grip for cassette tray
13 Foot treadle for table top break
14 Foot treadle for motorized lowering of the table top
15 Foot treadle for motorized raising of the table top
16 Emergency stop switch
17 Switch for table mode
18 Switch for wall mode
19 Switch for small SID in wall mode
20 Switch for large SID in wall mode
21 Switch for tomo mode
22 Prep-switch for driving in central position
23 Switch for test run
24 Switch for selection of exposure angles
25 Switch for reducing the tomo height
26 Switch for increasing the tomo depth
27 Switch for selection of exposure time
28 Control panel display

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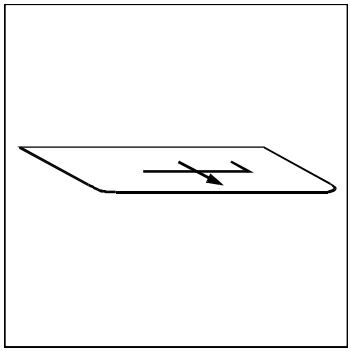
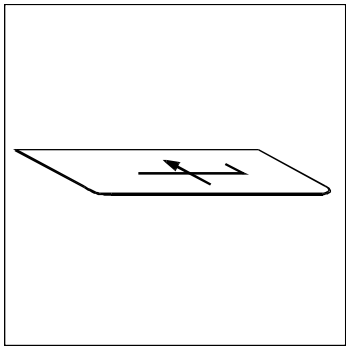
Meaning of Symbols/Function



Foot switch **14** and security switch **6a** for motorised lowering of the table top. The table is moving down as long as the switches are pressed.
The lowering speed with soft start and break is constant. Automatic shutdown of the down motion in end position and in exposure height. Continue of movement after interruption in exposure height.

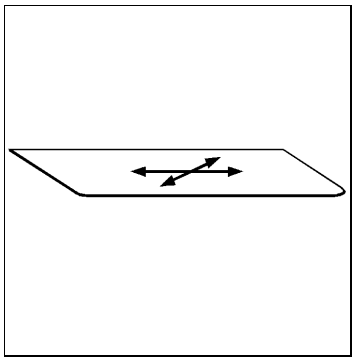
Release foot switch/security switch. Push again.



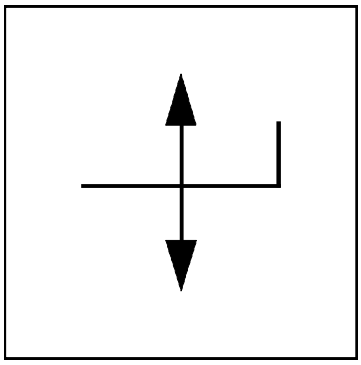
Foot switch **15** and security **6a** for motorised raising of the table top. The table raises as long as the switches are pressed.

The raising speed with soft start and break is constant. Automatic shutdown of the up motion in end position and exposure height.

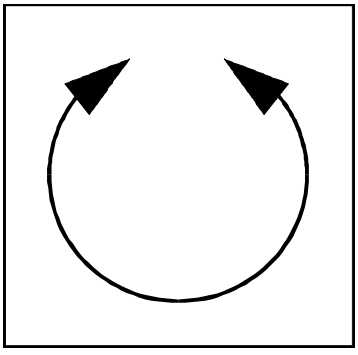
Release foot switch/security switch. Push again.



Foot switch **13** to release the brakes of the floating table top. The table top can be manually shifted longitudinally and transversely as long as the switch is depressed. The table top locks in place when the switch is released.



Security switch **6a** for motorised raise respectively lowering of the table top.



Switch **6**
to release the brakes for the rotation movement of the X-ray tube. Release of the switch locks the tube in position.

By turning the x-ray tube close to the 0° and 90° position, the LED blinks. Release of the switch causes a exactly motorized positioning of the x-ray tube.

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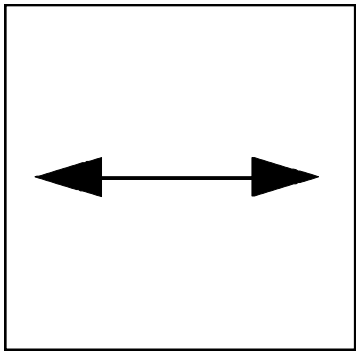
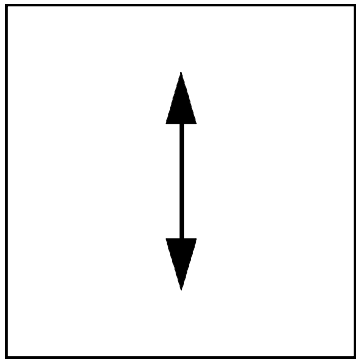
Switch **4**

unlocks the column brake for longitudinal movement. Release of the switch locks the column in place.



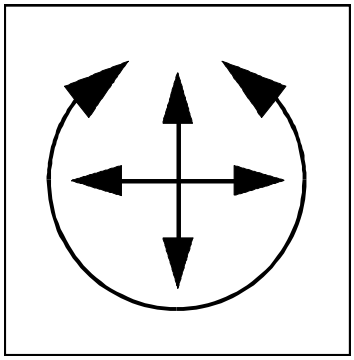
Switch **5**

unlocks the vertical carriage. Release the switch and the vertical carriage will be locked in place again. The motion stops automatically at the preferred vertical SID and can be continued by pressing the switch agin. The motion stops automatically at the preferred vertical SID and can be continued by pressing the switch again.



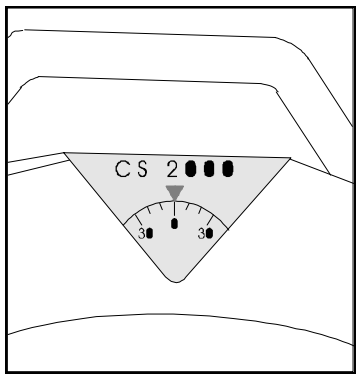
Switch **7**

unlocks the column brakes. Release of the switch locks all movements in place.



Protractor **9**

indicates the angle of the tube vs. Exposure object.



Indicator LED (green) **1**

lights up to indicate that the Bucky is centered to the column .

Indicator LED (green) **2a**

lights when the table top is in exposure height.

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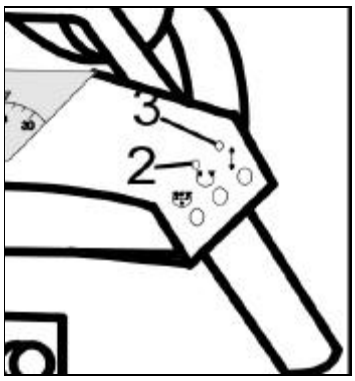
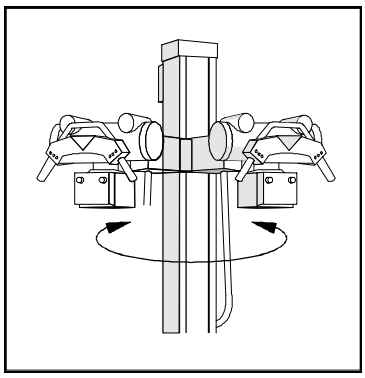


Indicator LED (green) **2**

indicates an exactly 0° or 90° positioned x-ray tube
(not in Tomo mode)

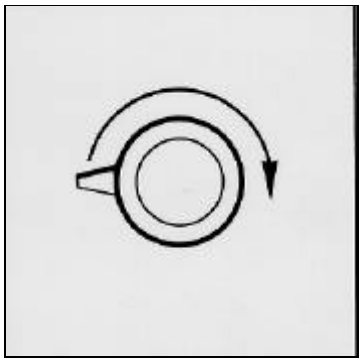
Indicator LED (green) **3**

indicates the adjusted vertical SID



Rotation of column **10**

The column can be turned about his vertical axis by abrupt movement on the control handle.
It is locked at 0° and 90° left and right.



Emergency Stop switch **16**

The Emergency Stop switch has to be pressed immediately if there is any risk of injury for the patient, operator or the unit. Resetting the stop switch by turning the button to the right is only allowed when the risk of injury is surely eliminated.

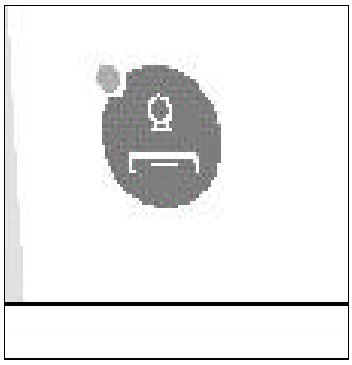
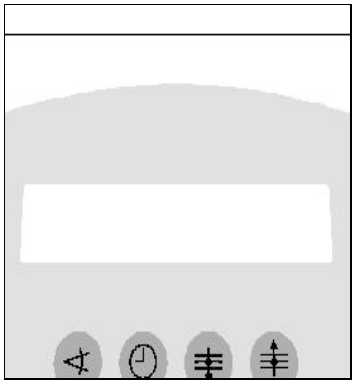


Table mode switch **17**

for selection of table mode. As soon as the table mode is activated, the SID lights up. While travelling the tube stand, the Bucky in table range and the X-ray tube will follow and centered automatically. Both SIDs 1 and 2 light up when the centering has been taken place.



Control panel display **28**

The indication in the display will guide the operator through the programme respectively shows the operator the working steps. Errors in Tomo mode will be shown with error message EXX. Switch - off unit as soon as error lights - up and switch - on again after approx. 3 minutes. If the error still lights - up please contact your service support.

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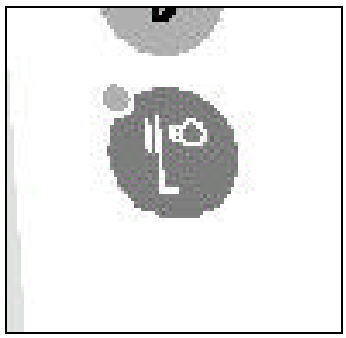
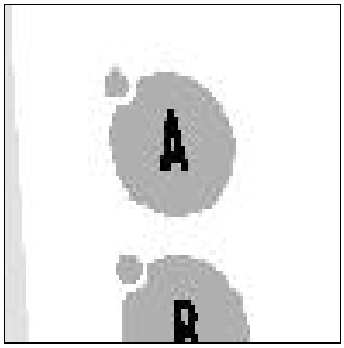
Switch **18**

for selection of wall mode. As soon as the wall mode is activated, the LED lights up.



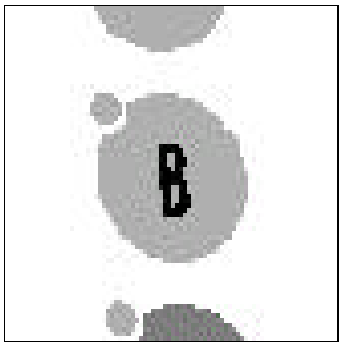
Switch **19**

for motorised start of the adjusted small SID.
Attention: The motorised start is only possible when the X-ray tube is on the vertical preferred SID and the green LED3 lights up.
The tube stand drives on the SID and the X-ray tube rotates in direction of wall stand as long as the switch **19** is pressed.
When the SID is reached, the LED at the switch lights up.



Switch **20**

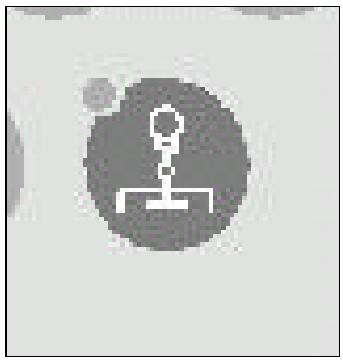
for motorised start of the adjusted large SID.
Attention: The motorised start is only possible when the X-ray tube is on the vertical preferred SID and the green LED 3 lights up.
The tube stand drives on the SID and the X-ray tube rotates in direction of wall stand as long as the switch **20** is pressed.
When the SID is reached, the LED at the switch lights up.



Switch **21**

for selection of tomo mode.
The LED lights up as soon as the tomo mode is activated.

Attention: The motorized mouvements are only possible, if the table is at the exposure height, the preferred vertical SID is adjusted and the colunm is locked at the 0° position.



Prep-switch **22**

for drive of column, Bucky and for rotation of the X-ray tube in central starting position.

Attention: Only in this central position, the tomo parameters can be selected.
The Prep-switch always has to be pressed after switching on the unit (when it`s not at the central position) and after selection of tomo mode.

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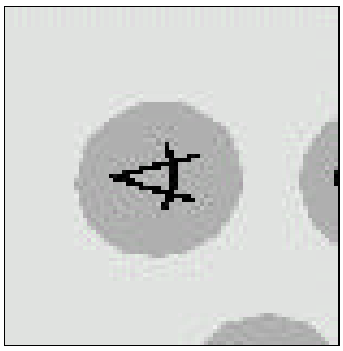
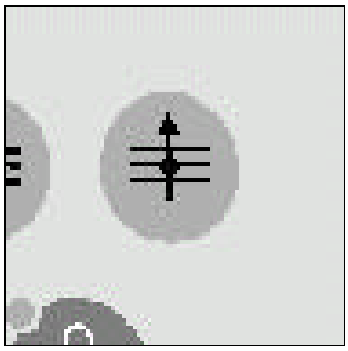
Switch **23**

for performance of a test run respectively for drive in exposure position after selection of tomo parameters.
Attention: The tube stand will stay in exposure starting position for approx. 1 sec. during test run. The test run starts and ends in central position.



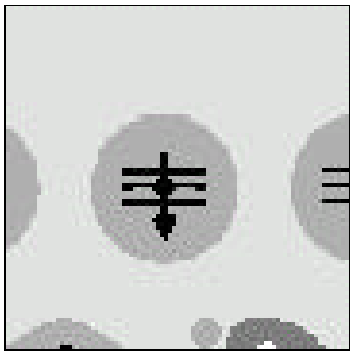
Switch **24**

for selection of tomo angles.
Attention: Only possible in central position.



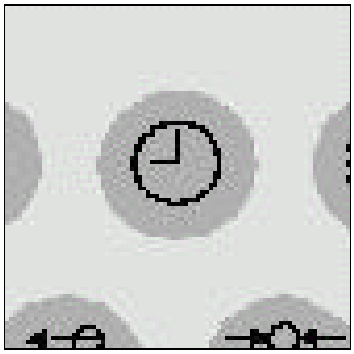
Switch **25**

for increasing the tomography layer height in mm steps.
Attention: Only possible in central position.



Switch **26**

for reducing of the tomography layer height in mm steps.
Attention: Only possible in central position.



Switch **27**

for selection of the tomography exposure time.

Attention: Only possible in central position.

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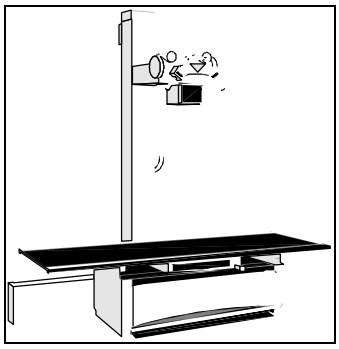
SETTING EXPOSURE POSITION/EXPOSURE

Patient Positioning/ Centering of Bucky, Object and Tube Unit.

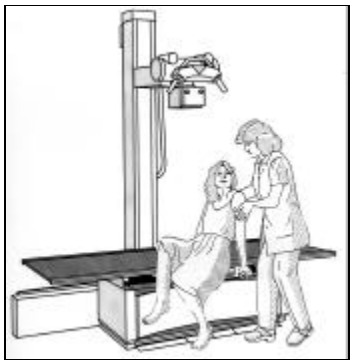
Patient Positioning



Press the foot switch **13** to unlock the table top brakes.

Move the table top manually floating to the rear stop.

Release the foot switch.

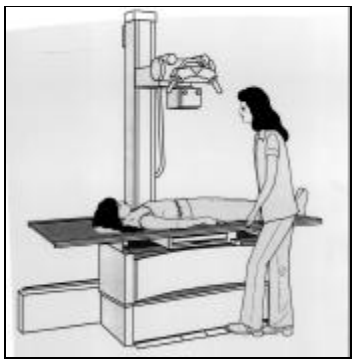


Press the foot switch **14** and the safety switch **6a** simultaneously. The table top is lowered by the motor in a telescopic way.

Release the switch when comfortable working height for patient access or transfer is reached.

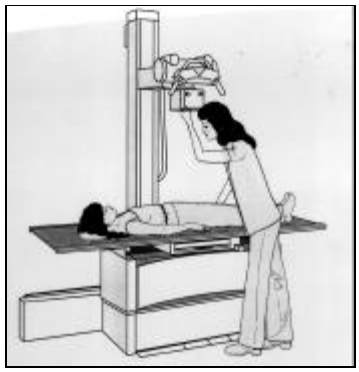
Note
When reaching the preset exposure position of the table top, the downward movement is interrupted automatically. To continue movement, release the foot switch. Press again.

Exposure



Press the foot switch **15** and the safety switch **6a**. The table top is lifted up by the motor to exposure position. Release the switch after the automatic stop.

Exposure in table mode



Push switch **17** on control panel, the green LED lights up. Push switch **7** on control arm and drive the X-ray tube to the preferred SID (green LED **3** lights up) and the tube stand with tube to the middle of the table. The centering respectively adjustment of the Bucky will go automatically, when the column will be moved the X-ray tube is in 0° position and the column is in travel range of Bucky. The LED **1** lights up, when tube and Bucky are centered.

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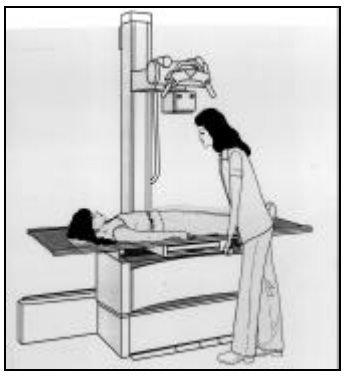
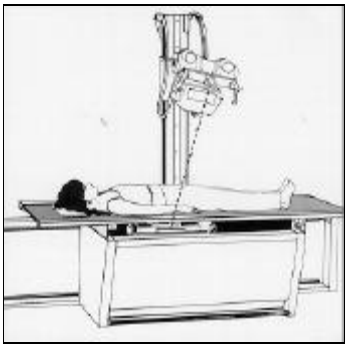


Centering of patient and beam field

Collimate the x-ray beam to film size (field light, manual of collimator)
Move the table top with the patient after actuating foot switch **13** under the light field. Releasing the foot switch **13** locks the table top.

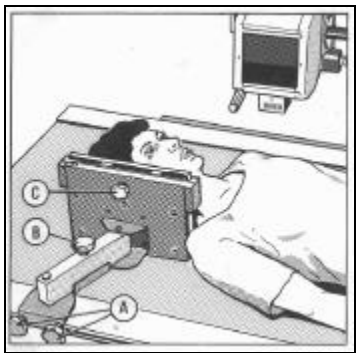


Adjustment of angular exposure

Move column to the needed position. Adjust Bucky while pressing push button **11** under exposure object. Rotate X-ray tube and center with switched-on optical pointer of the collimator to middle of Bucky.

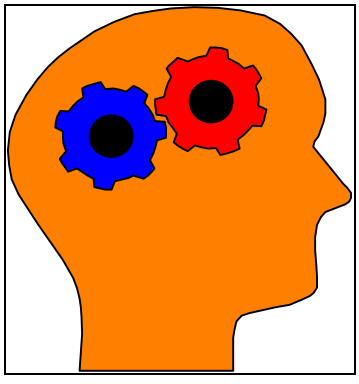
Exposure with Bucky wall stand

Move table top in the opposite direction of Bucky wall stand. Push with switch **18** in wall mode, the LED lights up. Press **20** or **21** (depending on SID) and keep depressed, the X-ray tube rotates automatically in direction of wall stand and column stand to the required SID. The tube stand can be moved manually too. Then it stops automaticlly at the SID. Drive Bucky of the wall-stand in the vertical corresponding to exposure object. Switch on light and adjust X-ray tube for centering while pressing switch **5.**



Lateral exposure

Rotate tube stand and X-ray tube by 90° (protractor) when lateral exposure with side cassette holder (see also accessories) is required.



Exposure preparation

Insert cassette. Choose SID (FFD). Set exposure dates on control desk. Control readiness for exposure. Command patient to „hold your breath“.
Note
Do not forget radiation protection devices for the patient (lead rubber apron, gonad protection, etc.)

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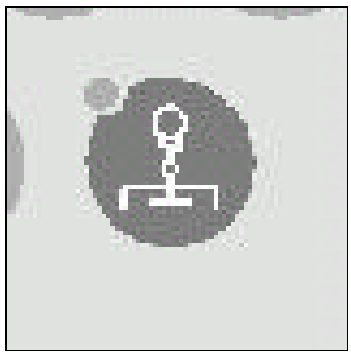
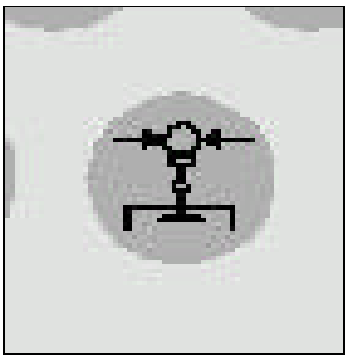
Adjustment of tomography (in tomo mode)



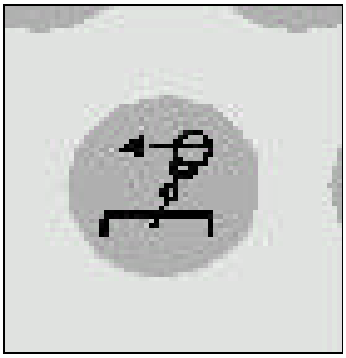
Position patient on table.

Remark: Before positioning of patient move tube stand with X-ray tube so that patient cannot be hurt while getting up or laying down !
Drive table to the exposure height.
Drive X-ray tube to the preferred SID while pressing switch on the control arm, the LED lights up.

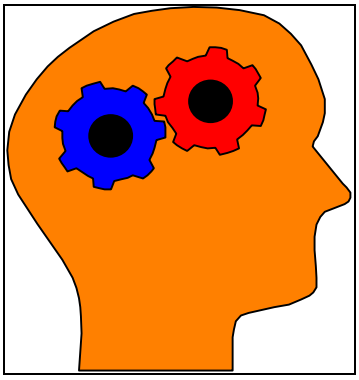


Choose with switch 21 the tomo mode.

Press prep-switch **22** and keep depressed until the column, stops in central position and the tomo parameters are shown on the display.
Remark: Column, Bucky and tube cannot be moved manually in tomo mode.
Choose tomo parameters (tomo angle, exposure time, and tomography layer height).
Press test switch **23** for performance of a test run.
Fade-in light field of collimator to film size and switch-on.
Adjust exposure object to the light field. Put cassette in Bucky.
Drive column in exposure start position with switch **23** or start test run.



Exposure preparation



The exposure can only be triggered at the generator. Set exposure dates on control desk. Control readiness for exposure.
Command patient to „hold your breath“.Press the generator`s exposure switch until the exposure is finished.
Note:
Do not forget radiation protection devices for the patient (lead rubber apron, gonad protection, etc.)

Attention: If the exposure is interrupted or another exposure shall be made, the tube stand has to be moved to the central position by pressing the prep-switch. After selection of the tomo parameters the unit is ready for a new exposure. It`s possible to drive to the start position with the first step of the generator`s exposure switch.

Attention: The operator has to observe the patient and the motion of the unit during test run and exposure and has to stop immediately if there is any danger.

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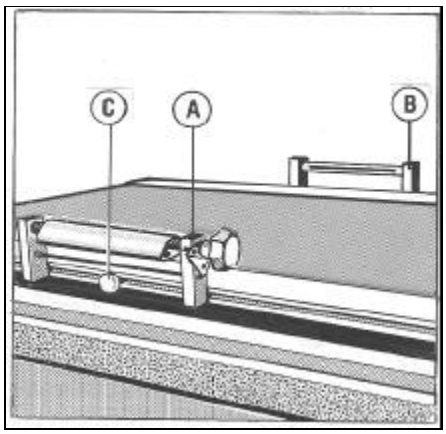
Accessories

Compression Belt / Head Supports / Hip Clamps / Table Mattres

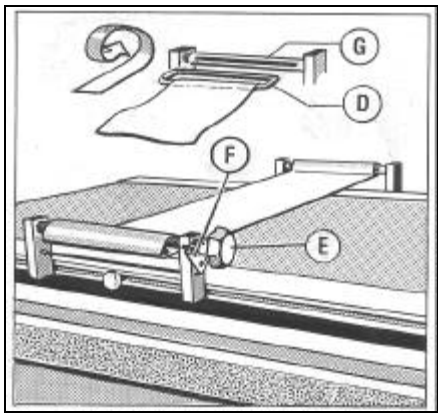


Compression Belt

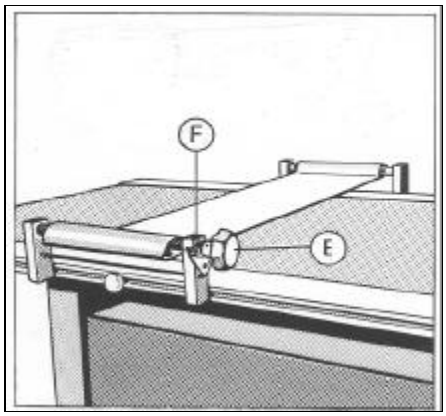
Fastening and application:

Slide support frame **B** into profile rail at wall side or into Bucky profile rail. Turn knob screw to clamp in position.

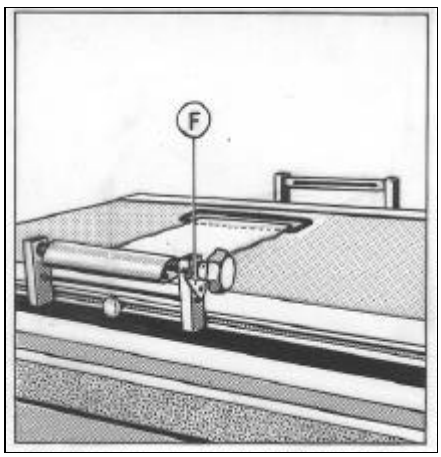
Slide tightener **A** into front profile rail (operator side). Turn hand screw **C** to clamp in working position opposite of **B**



Press ratchet mechanism **F**. Unroll belt and stretch across patient.



Guide belt through complementary frame and once around frame bar. Fix belt bracket **D** into slot of shaft **G**. Turn ratchet mechanism **E** to tighten belt.



Untightening:

Press locking lever **F**

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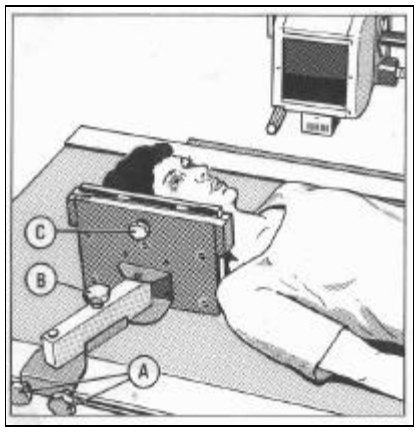
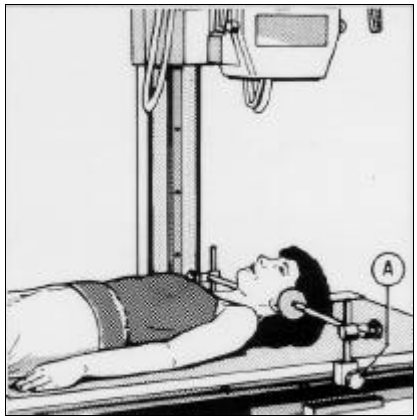
Lateral cassette holder



The lateral cassette holder permits lateral exposures if the tube unit is mounted to a tube swivelling device. The lateral cassette holder is slipped in one of the profile rails.

Grip screw (A): secures the holder at the table top
Grip screw (B): locks the holder setting
Grip screw (C): fixes the lateral position of the cassette clamps.

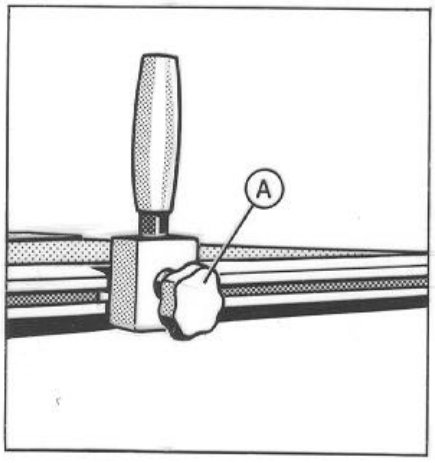
Head Supports



The head supports slide into profile rails of the table or Bucky. The supports can be clamped in any position desired. The patient`s head is fixed to the appropriate exposure position by cushioned plates on adjustable bars.
Hand screw **A**: Clamping head supports to table top or Bucky.

Hand screw **B**: Clamping of head holder

Hand grips



The hand grips are slipped in the profile rails of the table. They may be fixed at any position and offer a reliable hold for the patient.

Grip screw (**A**): secures the grip in place

Important note:

The positioned patient may only hold on to the hand grips. In no case may he put his hands around the edge of the table top.

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Maintenance:

Important note:
Like all technical equipment, this unit requires also a regular maintenance service to increase the safety of the equipment.

Operator´s service and maintenance

The operator has to check the x-ray equipment for defects as listed below:

Daily routine checks

Before operating check all functions of the indicator lamp, the operating elements, the brakes and movements. Please check existence and legibility of the inscription and warning signs.

In case of functional defects or other deviations from the normal operation the equipment has to be switched off at once and the service company has to be informed.
The equipment can not be used before all defects have been eliminated.

Weekly checks

Check all cables and their connections for treaces of wear.

Periodic maintenance

For trouble-free operation of the COMBI ELEVATOR TOMO-2 as well as safety for patient and user it is necessary to carry out a technical maintenance from the service company every 12 months.

Please see „technical maintenance“ of the mounting instruction.
The steel rope of the column has to be replaced every three years.

Attention:
In case of failure from components, which can limit the safety of the equipment, original spare parts have to be used.

We recommend that the service personnel is being asked to issue a certificate specifying the kind and extend of work that was done. Also the certificate should show the date of repair, the name of the service company and the signature of the technician.

Cleaning:

The equipment must be switched off before cleaning. Plastic surface should only be cleaned with mild soap. Do not use strong cleaners or solvents as they will damage the finish or blur the lettering.

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At least once a month external parts and exposed tracks on which rollers move should be wiped to remove foreign material that may have accumulated.
DO NOT USE A DAMP CLOTH.
Wipe the tracks with a cloth lightly soaked with light machine oil or WD-40.

To protect the finish, polish the equipment with PURE liquid paste wax. Do not use wax containing a cleaning substance. Polish all enamelled metal surfaces.

Disinfection:

The equipment has to be switched off before disinfection. Only disinfection methods can be used that correspond to the relevant regulations and rules as well as the protection for explosion.
Spray disinfection is not recommended because it can get in the inside of the x-ray equipment.

The Council Directive 93/42/EEC on Medical Devices

Article 12

This document is revised at the moment by the council.

However the Article 12 must be followed by the company or the legal person who put this X-ray unit into work.

The user is responsible for compliance and implementation of national deviations in the EU.

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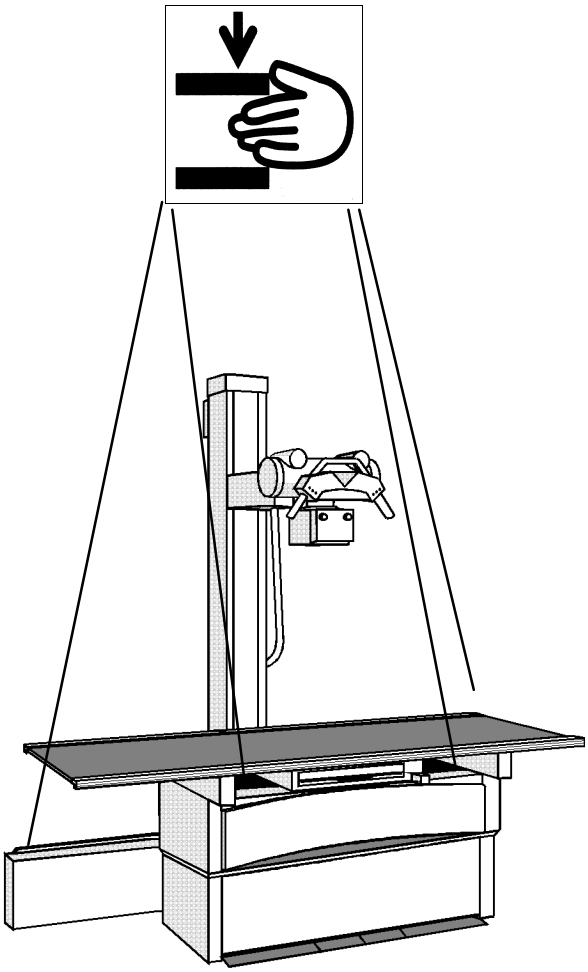
Name Plate Location:

Labeling:



Specifications are subject to change without notice. TV/Ru

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